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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/772,809
Filing Date: February 05, 2004
Appellant(s): BERNSTEIN, JOEL E.

Alice O. Martin
Reg. No. 35601
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/21/2010 appealing from the Office action mailed 8/21/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: 9, 11, 12, 14, 15 and 17.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection To Be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

4,579,846	Crawford	04-1986
WO 98/50044	Caruso	11-1998

Matheson A.J. "Rofecoxib: A Review of its Use in the Management of Osteoarthritis, Acute Pain and Rheumatoid Arthritis". Drugs 2001 May; 61(6): 833-865.

(9) Grounds of Rejection

Claim Rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crawford et al. (US Patent 4,579,846).

Crawford et al. teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant; see abstract and column 3, lines 45-58, in particular). Crawford et al. teaches that piroxicam

and doxepin are co-administered in a single, combined formulation (see column 3, lines 55-60, in particular). Crawford et al. also teaches that in a combined formulation, the proportion of each drug is the ratio of the total daily dosage of each drug when dosed alone (see column 3, lines 55-68, in particular). Crawford et al. exemplifies a treatment composition comprising piroxicam and 20 mg doxepin with lactose and hydroxypropyl methylcellulose in a capsule (carriers; see Examples 7 and 9 and column 4, lines 1-10, in particular).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the intended use recited in claim 9, namely that the composition is for treatment of chronic pain is not afforded patentable weight.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al. (US Patent 4,579,846) as applied to claims 9, 11, 14-15 above and in view of Caruso et al. (WO 98/50044) and Matheson et al. (Drugs 2001 May; 61(6): 833-865).

Crawford teaches a pharmaceutical composition comprised of a tricyclic antidepressant and a non-narcotic analgesic as discussed above.

Crawford does not teach the physiologically acceptable acid addition salt of the tricyclic antidepressant.

Caruso et al. teaches that it is known to provide the anti-depressant doxepin as a pain-relieving agent in the hydrochloride salt form (see page 4, in particular).

Matheson teaches that commonly used non-narcotic analgesics such as rofecoxib are used at doses up to 500 mg/day (see Abstract; meeting the limitation of 0.5 gm in claim 17). Matheson compares rofecoxib to other non-narcotic analgesics such as ibuprofen and naproxen, and was found to be similarly effective, and the doses

used of ibuprofen and naproxen are 2400 mg/day and 1000 mg/day respectively see Osteoarthritis under Therapeutic Efficacy for example). Though the paper focuses on rofecoxib, it is compared to other common non-narcotic analgesics used in different treatment paradigms that are used in doses that fall within the range claimed in claim 17.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the hydrochloride salt form of doxepin taught by Caruso et al, in the composition of Crawford et al, because Crawford et al. teaches the combination formed in a capsule, whereas Caruso et al. teaches that the hydrochloride salt form is a suitable form for the administration of the pharmaceutical drugs. Further, it would be obvious to a person of ordinary skill in the art to provide doses of the non-narcotic analgesic in the range of 0.5 gm to 2.5 gm daily per the teachings of Matheson because Matheson teaches that doses of several non-narcotic analgesics fall within the range claimed for various types of pain. Accordingly, one of ordinary skill in the art would have been motivated to provide the hydrochloride salt form with the expectation of achieving a composition suitable for pharmaceutical administration and to also provide doses of non-narcotic analgesics that fall in the range of 0.5 gm to 2.5 gm daily because these are doses that are commonly used for the treatment of different types of pain.

(10) Response to Arguments

Appellants present arguments over the 35 USC 102(b) rejection over Crawford. In particular, Appellants argue that Crawford teaches large amounts of ingredients that

are optionally in a composition that are not within the scope of the "consisting essentially of" language of the present invention, which does not include all of these compounds and whose goal is pain relief and not to reduce GI irritation as taught by Crawford. Appellants feel that the definition of "consisting essentially of" excludes piroxicam and one would not consider teachings of Crawford when searching for a pain medication. Appellants assert that the previous arguments regarding the fact that the present composition is directed toward pain relief and Crawford's goal is to reduce GI irritation and discuss the meaning of a preamble.

In response to the above arguments, it is noted that independent claim 9 reads on a composition that broadly includes a low dose of a trycyclic antidepressant and a standard dose of a non-narcotic analgesic (which includes non-steroidal anti-inflammatory drugs or NSAIDs). Crawford teaches compositions that include piroxicam, which is a known NSAID, and doxepin, which is a known tricyclic antidepressant. The other optional elements that Crawford teaches in the composition are pharmaceutically acceptable carriers or diluents (Col. 4, lines 14-33). These elements do not materially affect the basic and novel characteristics of a composition; therefore, the elements do fall within the definition of "consisting essentially of". Further, Appellants have argued that the purpose of Crawford et al. is to decrease GI irritation and that the reference is not concerned with pain. As discussed in the rejection, a recitation of an intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it

meets the claim. In the instant case, Crawford et al. teaches compositions that contain the same active ingredients as claimed; therefore, the composition of Crawford would be capable of performing the intended use. There was no discussion of a preamble in the previous Office Action, only a discussion of the intended use which was addressed above.

In addition, Appellants argue that the dose range of the tricyclic anti-depressant is not in Crawford nor was it addressed in the previous Office Action. Appellants assert that Crawford teaches piroxicam with doxepin although separately administered and Crawford does not specifically teach that the compositions are exemplified as a standard dose and a low dose.

It is noted that the previous Office Action teaches that piroxicam and doxepin are co-administered in a single, combined formulation (Col. 3, lines 55-60) and Crawford exemplifies a treatment composition comprising piroxicam and 20 mg of doxepin (see page 3 spanning into page 4 of the Final Office Action). Therefore the previous Office Action did address a dose range of the tricyclic antidepressant and both active ingredients in one composition as well as a standard dose of a NSAID and a lose dose of the tricyclic antidepressant.

Appellants further argue over the 35 USC 103 rejection over Crawford in view of Caruso and Matheson. In particular, Appellants argue that Caruso teaches only an antidepressant with a NMDA receptor antagonist and does not include a NSAID. Appellants further argue that Matheson is simply a review of rofecoxib.

In response to the above arguments, it is noted that Caruso was used for the teaching that doxepin is provided in the hydrocholoride salt form. This is accomplished in compositions comprised of doxepin, a NMDA receptor antagonist and a NSAID. Matheson was used to teach standard doses of non-narcotic analgesics, including rofecoxib, ibuprofen and naproxen as well as others to establish standard doses of several non-narcotic analgesics that fall within the range claimed in claim 17.

(11) Related Proceedings Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/SREENI PADMANABHAN/

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/Shengjun Wang/

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